

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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04 MARS 2005

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

01.03.2005

Applicant's or agent's file reference
LDR/10/PCT

IMPORTANT NOTIFICATION

International application No.
PCT/IB 03/04872

International filing date (day/month/year)
31.10.2003

Priority date (day/month/year)
05.11.2002

Applicant
LDR MEDICAL

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:



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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference LDR/10/PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/IB 03/04872	International filing date (<i>day/month/year</i>) 31.10.2003	Priority date (<i>day/month/year</i>) 05.11.2002
International Patent Classification (IPC) or both national classification and IPC A61F2/44		
Applicant LDR MEDICAL		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.


☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 08.04.2004	Date of completion of this report 01.03.2005
Name and mailing address of the international preliminary examining authority:  <div style="margin-left: 10px;"> European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840 </div>	Authorized Officer Stach, R Telephone No. +49 30 25901-551



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/B 03/04872**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-8 as originally filed

Claims, Numbers

6-20 as originally filed

1-5 received on 14.02.2005 with letter of 10.02.2005

Drawings, Sheets

1-4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	6, 11-14, 18, 19
	No: Claims	1-5, 7-10, 15-17, 20
Inventive step (IS)	Yes: Claims	12, 13, 18
	No: Claims	6, 11, 14, 19
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/04872

Reference is made to the following documents:

- D1: US-B-6 368 3501 (GRIFFITH STEVEN L ET AL) 9 April 2002 (2002-04-09)
- D2: WO 01/01893 A (BEYERSDORFF BORIS ;MARNAY THIERRY (FR); SPINE SOLUTIONS INC (US)) 11 January 2001 (2001-01-11)
- D3: EP-A-0 560 141 (LINK WALDEMAR GMBH CO) 15 September 1993 (1993-09-15)
- D4: WO 00/74606 A (SDGI HOLDINGS INC ;ZDEBLICK THOMAS A (US); MCKAY WILLIAM F (US)) 14 December 2000 (2000-12-14)

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document) (see figures 19, 22-24 and column 5, lines 9-26 and column 8, lines 36-52):

An intervertebral disk prosthesis (200) comprising at least three parts including an upper plate, a lower plate, and a core (218), the upper convex surface of the core (see column 5, lines 9-26) being in contact with at least part (213) of the lower concave surface of the upper plate (see column 5, lines 9-26) and the lower surface of the core being in contact with at least part of the upper surface of the lower plate (206), and the upper plate being movable at least with respect to the core (218), wherein there are cooperation means (204, 207, 251, 271) not located in the middle of the core between the lower plate and the core, so as to limit or eliminate translation movements of the core (218) with respect to the lower plate along an axis substantially parallel to the lower plate, and to limit or eliminate rotation movements of the core (218) with respect to the lower plate, around an axis substantially perpendicular to the lower plate, the planes passing through the upper and lower plates forming a substantially constant angle.

- 1.1 Furthermore each of the documents D2, D3 and D4 discloses all the technical features of claim 1.
2. Dependent claims 2-11, 14-17, 19 and 20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/04872

of the PCT in respect of novelty and/or inventive step.

3. The combination of the features of dependent claim 13 is neither known from, nor rendered obvious by, the available prior art. Dowel pins and wells located in the vicinity of the centre of the lower plate make the connection between lower plate and the core safer since the possibility of damage caused by surrounding tissue or instruments during the implantation is reduced.

1.